

REMARKS

In accordance with 37 C.F.R. § 1.121, a marked up copy of the presently amended paragraph of the specification is appended hereto. Deletions to the originally filed text are noted by bracketing. Additions are noted by underlining.

The Commissioner is hereby authorized to charge any fees for this submission that may be incurred or credit any overpayment of fees to Deposit Account No. 50-1273. The Examiner is invited to contact Applicants' undersigned Representative if it is believed that prosecution may be furthered hereby.

Respectfully Submitted,

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By: _____


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anti-Human κ or λ -HRP (Fischer, Pittsburgh, PA) 1:2000 in TBSB, 100 μ l was added to wells, and incubated for 1 hour at 22 °C. The wells were washed 6 times with 200 μ l TBST. One hundred μ l of substrate (TMB 1 component, KPL Inc., Gaithersburg, MD) was added to wells, developed 30 min. and assayed at OD₆₂₀.

- 5 d. **Idiotypic Protein Release Criteria:** (1) The DNA sequence of
idiotype-variable genes in baculovirus from production supernatant must be identical
to the DNA sequence in the production vector. (2) The idiotypic protein concentration
was greater than 0.5 mg/ml based on OD₂₈₀. (3) The major peak area was greater than
90% of area in evaluated peaks on Superose 6 analytical chromatography. (4) The
10 major chromatographic peak corresponds to the human IgG κ (or λ) ELISA activity
peak.

The final vaccine product, Id-KLH, was tested for endotoxin levels by a kinetic
turbidity microplate assay or a Limulus Amoebocyte Lysate (LAL) assay and had a
level below 350 endotoxin units (EU) per ml. Ten percent of the lot was tested for
15 sterility on a 14-day test and tests negative or was discarded.

Table 3 shows a summary of primer sequences used for establishing final
product identity.

TABLE 3. Primer Sequences Used for Establishing Final Product Identity.	
PRIMER NAME	PRIMER SEQUENCE (5' 3')
1. Human Placental Alkaline Phosphatase Internal	AAATGATAACCATCTCGC (SEQ ID NO:25)
2. Human Placental Alkaline Phosphatase External	TTTACTGTTTTTCGTAACAGTTTTG (SEQ ID NO:26)
3. Kappa Light Chain Constant Antisense	TTGGAGGGCGTTATCCACCTTC (SEQ ID NO:27)
4. Kappa Light Chain Constant Downstream Internal	CTGTAAATCAACAACGCACAG (SEQ ID NO:28)

5. Kappa Light Chain Constant Downstream External	CAACAACGCACAGAATCTAG (SEQ ID NO:29)
6. Melittin Internal	GGGACCTTTAATTCAACCCAACAC (SEQ ID NO:30)
7. Melittin External	AAACGCGTTGGAGTCTTGTGTGC (SEQ ID NO:31)
8. IgG _{γ1} Heavy Chain Constant Downstream Internal	GGAAGTAGTCCTTGACCAGGCAG (SEQ ID NO:32)
9. IgG _{γ1} Heavy Chain Constant Downstream Middle	CTGAGTTCACGACACCGTCAC (SEQ ID NO:33)
10. IgG _{γ1} Heavy Chain Constant Downstream External	TAGAGTCCTGAGGACTGTAGGAC (SEQ ID NO:34)
11. Kappa & Lambda Downstream:	5'-GGTCGTTAACAATGGGGAAGCTG-3' (SEQ ID NO:35)
12. PH forward	5'-TTTACTGTTTTCGTAACAGTTTGTG-3' (SEQ ID NO:36)
13. PH reverse	5'-GGTCGTTAACAATGGGGAAGCTG-3' (SEQ ID NO:37)
14. Lambda Constant Internal	5'-GAAGTCACTTATGAGACACACCAG-3' (SEQ ID NO:38)

5 8. **USE OF CHIMERIC PROTEIN OF THE INVENTION FOR
TREATMENT OF NON-HODGKIN'S B-CELL LYMPHOMA:**

V_H and V_L regions were obtained from a patient with Non-Hodgkin's B-Cell Lymphoma. Using the 5' RACE method described *supra*, genes encoding these regions were cloned and inserted into the expression vector and expressed by the methods of the instant invention. Table 5 contains the DNA sequences of the V_H and V_L regions used for the expression vector. The Apa I and Dra III sites used for cloning are indicated by underlining.

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